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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Udo Krupka

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

10/07/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,345	Applicant(s) KRUPKA, UDO	
	Examiner AGNIESZKA BOESEN	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 24-30,33-46 and 49-55 is/are pending in the application.
- 5a) Of the above claim(s) 36-39 and 41 is/are withdrawn from consideration.
- 6) ☒ Claim(s) 24-27,29,43-46,49,50 and 53-55 is/are allowed.
- 7) ☒ Claim(s) 28,30,33-35,40,42,51 and 52 is/are rejected.
- 8) ☒ Claim(s) 29 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/10/11 and 5/11/2010</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/11/2010 has been entered.

Claims 28 and 39 have been amended. New claims 52-55 have been added. Claims 36-39 and 41 are withdrawn. Claims 24-30, 33-35, 40, 42-46 and 49-55 are under consideration.

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Art Unit 1648.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 2/10/2011 and 5/11/2010 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

Applicant's argument regarding the rejoinder of withdrawn claims 26, 27, 43-45, 49 and 50 is found persuasive and thus the claims are rejoined and under consideration.

Specification

The objection to the specification present in the Office action on 1/11/2010 is withdrawn in view of Applicant's amendment.

However a new objection is made, on the same basis as the previous objection, in view of Applicant's amendment to the claims. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification lacks antecedent basis support for the limitations of (e.g.) claim 28 with respect to the positions 93-151 of SEQ ID NO: 12 in which the claimed fragments must be found, and claims 52-55 with respect to the positions 69-77, 74-82, 108-116, 118-126 and 135-143 of SEQ ID NO: 12. The specification does not provide antecedent basis for the language referring to the recited regions presented in the amended claims.

Claim Rejections - 35 USC § 102

Rejection of Claims 28, 30, 33, 40 and 51 under 35 U.S.C. 102(b) as being anticipated by GenBank AAF36498 **is withdrawn** in view of Applicant's amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Rejection of Claims 28, 30, 33, 40, and 51 under 35 U.S.C. 102(a) as being anticipated by GenBank AAO41333 **is maintained**.

Applicant's submission of the English translation of the foreign priority document, German Application No. 103 28 080.4 filed June 20, 2003 is acknowledged. However the present claims 28, 30, 33, 40 and 51 are not granted priority date of the German Application No. 103 28 080.4 filed June 20, 2003 because the limitations regarding the specific amino acid positions, 5, 6 and 8 amino acid long peptides and the specific regions recited in the claims are not found in the foreign priority document. The SEQ ID NO: 12 is present in the German Application No. 103 28 080.4 however, there is no mention about the specific amino acid positions, 5, 6 and 8 amino acid long peptides and the specific regions of SEQ ID NO: 12 recited in the claims.

Rejection of record is reiterated below:

Claims 28, 33, 40, and 51 read on a polypeptide comprising a fragment of SEQ ID NO: 12, the fragment comprising at least 6 amino acids found within the sequence of residues 107-117 of SEQ ID NO: 12 and comprising the amino acid of position 112 of SEQ ID NO: 12 (L112). This sequence of residues 107-117 is found in residues 323-333 of the sequence disclosed by the indicated GenBank sequence. Claim 30 requires that the polypeptide reacts to sera from a patient infected with HBV variant HDB 05. Because the sequence disclosed by the reference includes the sequence of claim 28, the sequence would also be capable of reacting to sera directed to the shared sequence, and thus meets the requirements of claim 30. The reference therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claims 34, 35, and 42 under 35 U.S.C. 103(a) as being unpatentable over GenBank AAO41333 as applied to claim 28, and further in view of U.S. 5,856,084 **is maintained.**

Applicant's submission of the English translation of the foreign priority document, German Application No. 103 28 080.4 filed June 20, 2003 is acknowledged. However the present claims 28, 30, 33, 40 and 51 are not granted priority date of the German Application No. 103 28 080.4 filed June 20, 2003 because the limitations regarding the specific amino acid positions, 5, 6 and 8 amino acid long peptides and the specific regions recited in the claims are not found in the foreign priority document. The SEQ ID NO: 12 is present in the German Application No. 103 28 080.4 however, there is no mention about the specific amino acid positions, 5, 6 and 8 amino acid long peptides and the specific regions of SEQ ID NO: 12 recited in the claims.

The rejection of record is reiterated below

These claims read on methods for the recombinant expression of the claimed proteins or the use of such for the detection of anti-HBV antibodies.

The GenBank references teach HBV S and pre-S proteins comprising the claimed HBV S antigen sequences. However, the reference does not teach the methods of the presently rejected claims.

The patent teaches that the HBV S and pre-S antigens are useful in immunoassays, including assays for the detection of anti-HBV antibodies. Cols. 1-2, and 8. While the teachings of the patent are specifically directed to the use of particular HBV mutant S antigens, it would have been apparent to those of ordinary skill in the art that the unmodified proteins of the GenBank references could also be used in such methods. In view of such teachings, it would have been obvious to those of ordinary skill in the art that the antigens of the GenBank references could be used as HBV antigens in such assays.

In addition, the patent also teaches that HBV antigens may be recombinantly expressed through methods such as those described by claims 34 and 35. See e.g., column 7. It would therefore also have been obvious to those of ordinary skill in the art to use such methods for the production of the HBV proteins of the GenBank references.

The presently claimed methods are therefore obvious over the teachings of the prior art.

New Rejection

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank AAO41333 and GenBank AAF36498.

Claim 52 requires two peptides, one peptide comprising at least 5 amino acids found within the sequence of residues 108-116 of SEQ ID NO: 12 and comprising position 112 of SEQ ID NO: 12 (L112) and a peptide comprises 5 amino acids and comprising claimed residues 118-126 of SEQ ID NO: 12 and comprising 112 position (V112) .

Art Unit: 1648

GenBank AAO41333 sequence comprises 5 amino acid peptide comprising claimed residues 108-116 of SEQ ID NO: 12 and leucine at position 112 of present SEQ ID NO: 12 (see residues 323-333 of the sequence disclosed by the indicated GenBank AAO41333 sequence.

GenBank AAF36498 sequence comprises 5 amino acid peptide comprising claimed residues 118-126 of SEQ ID NO: 12 and comprises amino acid valine at position 122 of present SEQ ID NO: 12 (see positions 163-167).

It would have been *prima facie* obvious to provide GenBank AAO41333 sequence comprising 5 amino acid peptide comprising claimed residues 108-116 of SEQ ID NO: 12 and leucine at position 112 of present SEQ ID NO: 12 and 5 amino acid peptide taught by GenBank AAF36498 sequence comprising 5 amino acid peptide comprising claimed residues 118-126 of SEQ ID NO: 12 and comprises amino acid valine at position 122 of present SEQ ID NO: 12 (see positions 163-167).

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

Objection to Claims 47 and 48 under 37 CFR 1.75 as being substantial duplicates, respectively of claim 25 and 46 is withdrawn because Applicant canceled the claims.

Conclusion

Claims 24-27, 29, 43-46, 49-50, and 53-55 appear to be allowable over the prior art. Claim 29 is objected to for depending from a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/
Primary Examiner, Art Unit 1648